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ON

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,716	01/11/2001	Ronald Alan Coffee	BER-3.5.009/3714	1036

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GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE  
1 RIVERFRONT PLAZA  
NEWARK, NJ 07102-5497

EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/28/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/758,716

Applicant(s)

COFFEE, RONALD ALAN

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/11/01, 8/1/01, 9/11/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 11, 15, 16, 18-23 and 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 12-14, 17, 24, 25 and 29-41 is/are rejected.
- 7) ☒ Claim(s) 26 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

## **DETAILED ACTION**

### **Summary**

**It appears as if a Preliminary Amendment was filed instructing the office to add the continuing data and a new abstract to the specification. However, only one page of the Preliminary Amendment has been found in the application. As such, the Preliminary Amendment has not been entered.**

**The examiner requests the submission of a duplicate Preliminary Amendment.**

### ***Information Disclosure Statement***

1. The information disclosure statements filed 1/11/01, 8/1/01 and 9/11/02 have been received and made of record in the application file wrapper. Note the acknowledged PTO -1449 forms.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "8" as shown in Fig. 4 and "j" and "c" as shown in Figs. 8 and 13. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Claim Objections***

3. Claims 8, 10, 11, 15, 16, 18-23 and 35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from

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another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims will not be further treated on the merits.

4. Claims 1-5, 14, 25, 28-31, 33, 34 and 41 are objected to because of the following informalities: the phrases "which comprises", "which further comprises" and "which method comprises" should read --comprising the step of-- or --further comprising the step of--, which ever is appropriate. Appropriate correction is required.

As regards claim 2, line 10 "deposit" should read --deposited--.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, claim 29 recites "...supplying liquid containing nitrocellulose at approximately four milliliters per hour to an electrohydrodynamic site located at about 5 to 10 cm above the surface", however, the specification does not disclose the distance being claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 27, the preamble does not agree with the preamble of claim 25, the claim from which it depends. As such, it is unclear to the examiner which method is being claimed, a method of forming a composite material or a method for forming a composite for covering a cavity wound.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 3, 30, 33, 37, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by XP 002046662.

Regarding claims 1 and 41, XP 002046662 discloses a method for forming at least partially solid material, comprising the step of subjecting a liquid at an outlet to an electric field, thereby causing the liquid to form at least one jet of electrically charged liquid (Abstract), the liquid being such that after formation said one jet forms a fiber or breaks up into fiber fragments or particles (Abstract).

Regarding claim 2, the method of XP 002046662 is concerned with covering or coating a surface using the method of claim 1.

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Regarding claim 3, the method disclosed by XP 002046662 is for direct dressing of an area such as, for example, a wound surface or the skin of a user.

Regarding claim 30, XP 002046662 discloses a device for performing the method as outlined in the rejection of claim 1, *supra*.

Regarding claim 33, it is inherent that the device is hand holdable for applying the product produced by the method of claim 3.

Regarding claims 37 and 39, the method disclosed by XP 002046662 produces a product comprising at least one fiber. The product can be defined as a "mat" or a "web" or a substrate, which carries electrohydrodynamically formed matter, since the terms used to describe the products made by a known method are of no consequence.

11. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 005 053 ("Bornat").

Regarding claim 4, Bornat discloses the method as claimed including the step of forming a tubular product for use on wounds by subjecting a liquid to an electric field (page 1, lines 15-23) at an outlet adjacent a substrate **capable** of being applied to a wound, thereby causing at least one jet of electrically charged liquid, the liquid being such that after formation the jet forms a charged fiber which is attracted to the substrate and deposits onto the substrate (Fig. 1).

12. Claims 5, 6, 13, 17 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 234 842 ("Bray et al.").

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Regarding claim 5, Bray et al. anticipate the method as claimed for inhaling the liquid (depositing into a cavity) fibers or liquid fiber fragments or droplets (note Figs 1-4 and claim 1).

Regarding claims 6 and 13, Bray et al. disclose a method for supplying the respiratory system of an animal with liquid having electrically discharged comminuted matter (i.e., the discharged matter is supplied to the respiratory tract from remote location), said matter having partially solid particles therein, since during the process of partial solidification, hardening of the comminuted matter will occur. Further, it is inherent that liquid would be discharged prior to supplying said liquid to the respiratory system.

Regarding claim 17, Bray et al. disclose the use of a polypeptide (page 16, line 5).

Regarding claim 31, Bray et al. disclose a device for producing material for supplying into a cavity of an animal by subjecting the material to an electrical field according to the method of claim 13.

13. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 234 841 ("Noakes et al.").



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Regarding claim 25, Noakes et al. anticipate a method of forming a composite comprising the steps of supplying first and second liquids separately and subjecting them to an electric field to form one liquid jet, the liquids being selected to mix together to form a single body of material (page 3, lines 53-page 4, line 5 and Fig. 5).

14. Claims 1, 7, 31, 32 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,043,331 ("Martin et al.").

As regards claim 1, Martin et al. disclose a method of forming at least partially solid material by subjecting a liquid at an outlet (col. 6, line 56) to an electric field causing the liquid to form at least one jet of electrically charged liquid, the liquid being such that after formation, the jet forms a fiber (col. 1, lines 13-23).

As regards claim 7, Martin et al. disclose that the formed fibers are collected to form a mat having a plurality of layers. As such, the method must have been repeated (col. 1, lines 28-56).

As regards claim 31, Martin et al. disclose a device for producing material **capable** of being supplied to a cavity or concave surface, comprising, a supply of liquid, means for subjecting said liquid to an electric field at an outlet to cause the liquid to form at least one jet of electrically charged liquid, the jet comprising charged matter in the form of fibers, particles, or fiber fragments (col. 1, lines 38-50). Martin et al. further disclose means for electrically discharging the charged matter before it reaches the cavity or concave surface (col. 6, lines 36-49).

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As regards claim 32, Martin et al. disclose the use of an air jet to remove the mat from the belt. As such the air jet is **capable** of assisting the supply of material to a cavity or concave surface.

As regards claims 37 and 39, Martin et al. disclose a product comprising a mat of fibers (abstract), thereby anticipating the invention. The applicant should note that in a product claim, non-distinctive characteristics, such as, for example, how the product is formed, are disregarded. As such, applicant's recitations of "...formed by electrohydrodynamically processing..." and "...electrohydrodynamically formed matter..." are disregarded.

As regards claim 38, note col. 2, lines 6-50, which discloses that the fiber mat is used to form a wound dressing.

15. Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,146,730 ("Sadek et al.").

As regards claim 40, Sadek et al. disclose a film enrobed unitary core medicament, which anticipates the claimed invention, note for example, claim 31.

The applicant is again reminded that in a product claim, the method of how the product is formed is disregarded.

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable Bray et al.

As regards claim 24, Bray et al. fail to disclose that the fibers comprise a biologically active material such as DNA coated or complexed with a liposome. However, on page 15, lines 21-28, Bray et al. disclose that any drug suitable for administration to the patient via the lungs for treatment of the lungs or for absorption into the blood stream in order to produce a therapeutic effect elsewhere may be used.

The applicant should note that it has been held that the selection of any material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 160).

As such, one having ordinary skill in the art would have found it an obvious design choice to use any drug, including DNA coated or complexed with a liposome, for their intended purpose.

### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-7, 12-14, 17, 24, 25, 30-34, 40 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 7-11, 14 and 23 of U.S. Patent No. 6,252,129 ("the '129 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims 1-2, 7-11, 14 and 23 anticipate application claims 1-7, 12-14, 17, 24, 25, 30-34, 40 and 41. The examiner concedes that the application claims are broader in scope, however, once a patent is received for a species of a more specific embodiment, the applicant is not entitled to a patent for the generic or broader invention.

***Allowable Subject Matter***

20. Claims 26 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. Claim 28 is allowed.

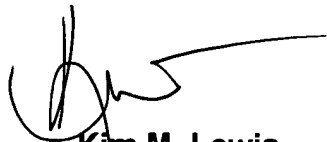
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is

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703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

A handwritten signature in black ink, appearing to be 'Kim M. Lewis', with a long horizontal stroke extending to the right.

**Kim M. Lewis**  
**Primary Examiner**  
**Art Unit 3761**

kml  
March 22, 2003